CERTIFICATE OF MAILING

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Date: November 15, 2002

Sean Mellino

Sean Mellino

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Robert Peter Klein, et al.
Serial No.	:	09/720,287 (Conf. No.: 1252)
Filed	:	May 10, 2001
Title	:	Transdermal Therapeutic System Containing Hormones and Crystallization Inhibitors
Examiner	:	Isis Ghali
Art Unit	:	1615
Attorney Docket	:	RO0208US (#90568)

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Washington D.C., 20231

MARKED UP PARAGRAPH

Example	Comp-arison	2	3	4	5	6	7
Durotak 387-2287	424.31	132.84	162.25	171.50	171.50	162.25	171.50
Oestradiol hemihydrate	3.37	1.34	1.34	1.34	1.34	1.34	1.34
Norethister-one acetate	21.60	8.65	8.65	8.65	8.65	8.65	8.65
Eutanol G	5.59	2.25	2.25	2.25	2.25	2.25	2.25
Al acetyl-acetonate	1.36	0.054	0.054	0.054	0.054	0.054	0.054
Ethyl acetate		36.48	29.28	27.11	27.11	29.28	27.11
Ethanol		36.48	29.28	27.11	27.11	29.28	27.11
Methyl ethyl ketone	134.79	--	--	--	--	--	--
[Euredur]	--	20.0	--	--	--	--	--

EUREDUR 145 - A curing agent for epoxide resins [Euredur]	--	--	5.0	--	--	--	--
EUREDUR 125 - A curing agent for epoxide resins [Euredur]	--	--	--	0.5	--	--	--
EUREDUR 250 - A curing agent for epoxide resins [Euredur]	--	--	--	--	0.5	--	--
EUREDUR 43 - - A curing agent for epoxide resins [Euredur]	--	--	--	--	--	5.0	--
EUREDUR 27 - - A curing agent for epoxide resins [Euredur]	--	--	--	--	--	--	0.5
EUREDUR 10 - - A curing agent for epoxide resins							

* * *

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MARKED UP CLAIMS

1. (Twice amended) A transdermal [Transdermal] therapeutic system in plaster form for controlled release of oestradiol in combination with norethisterone acetate, comprising:

a backing layer[,]; and

a reservoir supersaturated with active ingredients and containing oestradiol and norethisterone acetate, said reservoir is attached to said backing layer and is prepared using polyacrylate pressure-sensitive adhesives and crystallization inhibitors[,]; and is a detachable protective layer, wherein the crystallization inhibitor is an amino group -containing polymer selected from the group consisting of polyaminoamides,

polyaminoimidazolines, polyetherurethaneamines, polyamines, polyglucosamines and a copolymer based on butyl methacrylate, 2-dimethylaminoethyl methacrylate and methyl methacrylate being present in a molar ratio of 1:2:1 (butyl methacrylate : 2-dimethylaminoethyl methacrylate : methyl methacrylate).

3. (Twice amended) A transdermal [Transdermal] therapeutic system according to claim [Claim] 1, wherein the reservoir comprises at least one crystallization inhibitor in proportion of from 0.05 to 30% by weight.

4. (Twice amended) A transdermal [Transdermal] therapeutic system according to claim [Claim] 1, wherein the reservoir comprises oestradiol and norethisterone acetate in a weight ratio of from 1:2 to 1:15, and in an overall concentration of up to 25% by weight.

5. (Twice amended) A transdermal [Transdermal] therapeutic system according to claim [Claim] 1, wherein the reservoir includes a constituent from the group consisting of [ageing] aging inhibitors, plasticizers, antioxidants and absorption improvers, the plasticizers being used in a concentration of 0 [-] to 5% by weight and the [ageing] aging inhibitor in a concentration of 0.1 [-] to 2% by weight.

6. (Twice amended) A transdermal [Transdermal] therapeutic system according to claim [Claim] 1, wherein the pressure-sensitive adhesive is selected from the group consisting of a solvent-based adhesive, a dispersion adhesive, a hot-melt adhesive and a UV-crosslinkable adhesive.

7. (Twice amended) A transdermal [Transdermal] therapeutic system according to claim [Claim] 1, wherein the reservoir consists of at least two layers.

8. (Twice amended) A transdermal [Transdermal] therapeutic system according to claim [Claim] 1, wherein the reservoir has a layer thickness of 0.02 mm to 0.500 mm.

9. (Twice amended) A transdermal [Transdermal] therapeutic system according to claim [Claim] 1, wherein the reservoir is provided with an additional pressure-sensitive adhesive layer.

11. (Amended) A transdermal [Transdermal] therapeutic system according to claim 4, wherein the reservoir comprises oestradiol and norethisterone acetate in a weight ratio of from 1:3 to 1:7.

12. (Amended) A transdermal [Transdermal] therapeutic system according to claim [Claim] 8, wherein the reservoir has a layer thickness of 0.030 [–] to 0.200 mm.

13. (Amended) A transdermal [Transdermal] therapeutic system according to claim [Claim] 9, wherein the reservoir is provided with a pressure-sensitive adhesive margin.

14. (Amended) A transdermal [Transdermal] therapeutic system according to claim [Claim] 1, wherein the reservoir is provided with a pressure-sensitive adhesive margin.

15. (Amended) A method for providing a transdermal therapeutic system for therapeutic applications in human medicine, said method comprising:

applying said transdermal therapeutic system to the skin of a patient by applying a polyacrylate pressure- sensitive adhesive to said transdermal therapeutic system; and

controlling the release of oestradiol in combination with norethisterone acetate to the human skin by providing a reservoir in said transdermal therapeutic system, said reservoir being supersaturated with active ingredients and being attached to a backing layer, wherein said reservoir comprises at least one amino group-containing polymer and at least one adhesive selected from the group consisting of a polyacrylate pressure-sensitive adhesive layer and a pressure-sensitive adhesive margin.